

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
OFFICE OF FINANCIAL AND INSURANCE REGULATION
Before the Commissioner of Financial and Insurance Regulation

In the matter of

XXXXXX

Petitioner

v

File No. 121013-001

Blue Care Network of Michigan
Respondent

Issued and entered
this 17th day of October 2011
by R. Kevin Clinton
Commissioner

ORDER

I. BACKGROUND

On April 29, 2011, XXXXX (Petitioner) filed a request for external review with the Commissioner of Financial and Insurance Regulation under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.* The Petitioner receives health benefits through Blue Care Network of Michigan (BCN) under its *BCN 1 Certificate of Coverage*, and a BCN prescription drug rider.

The Commissioner notified BCN of the request for external review and requested the information used in making its final adverse determination. On May 3, 2011, BCN provided its response. On May 6, 2011, after a preliminary review of the material submitted, the Commissioner accepted the request for external review. On May 12, 2011 BCN submitted additional information.

The case involves medical issues so the matter was assigned to an independent review organization, which completed its review and sent its recommendation to the Commissioner on May 20, 2011. (A copy of the complete report is being provided to the parties with this Order.)

II. FACTUAL BACKGROUND

The Petitioner has Meniere's disease, a disorder which affects hearing and balance. She has tried a number of medications to treat her condition but claims none has worked as well as the compound prescription drug Betahistine which her doctor prescribed for her. BCN denied coverage for the drug because it is not approved by the Food and Drug Administration.

The Petitioner appealed BCN's decision through BCN's internal grievance process and issued its final adverse determination letter dated March 29, 2011.

III. ISSUE

Did BCN properly deny Petitioner coverage for Betahistine?

IV. ANALYSIS

Petitioner's Argument

The Petitioner explained in her request for external review:

I have Meniere's disease. After 6 months of suffering from severe symptoms my dr. finally prescribed the compounded drug betahistine. It has helped me tremendously & does not have all of the serious side effects of all the other drugs prescribed for me (like prednisone). Although it is currently not FDA approved the FDA has stated that it is SAFE! In fact it is prescribed pretty much worldwide. I hope to get this medication covered by BCN. I have found that other insurances are covering it, including Blue Cross-Blue Shield.

Respondent's Argument

In its March 29, 2011, final adverse determination, BCN denied coverage for Betahistine stating, "The [step two grievance] Panel . . . has completed its review of your grievance requesting authorization and payment for the [Betahistine powder] prescription drug. The Panel has maintained the denial because the requested medication is not approved by the U.S. Food Drug Administration (FDA)."

Commissioner's Review

The Petitioner's prescription drug rider excludes coverage for drugs that are experimental or not FDA approved:

There is no coverage under BCN drug riders for any drug which is experimental or which is being used for experimental purposes including but not limited to those regarded by the U.S. Food and Drug Administration as investigational.

The question of whether Betahistine was experimental or FDA approved for the treatment of Petitioner's condition was presented to an independent review organization (IRO) for analysis as required by section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6). The IRO reviewer is a physician in active practice who is certified by the American Board of Otolaryngology and is a member of the following professional organizations: the American Academy of Otolaryngology-Head and Neck Surgery, the American Medical Association, and the American College of Surgeons. The IRO reviewer's report includes the following analysis:

The benefit of the compound drug Betahistine in the treatment of Meniere's Disease has not been established as a standard of care in the medical literature and remains controversial; therefore, Betahistine is considered experimental for the treatment of Meniere's Disease as its benefits are not established and the drug's use is still being studied.

The standard of care for this enrollee's condition is to utilize medical management consisting of salt restriction, diuretics and the antihistamine meclizine. Intratympanic steroid and/or gentamicin injections and endolymphatic sac surgery may be utilized for medical failures. [Citation omitted]

* * *

Although recent peer-reviewed, published medical literature has indicated that there may be some benefit from Betahistine treatment of Meniere's Disease, many of the studies are not blinded and controlled and are thus flawed. Further investigation and study of this treatment are required to establish its benefit. Until this is accomplished, the use of Betahistine is considered experimental/investigational for this enrollee's condition, and therefore, cannot be considered medically necessary treatment at this time.

The Commissioner is not required in all instances to accept the IRO's recommendation. However, the IRO recommendation is afforded deference by the Commissioner. In a final order which rejects an IRO recommendation, the Commissioner must cite "the principal reason or reasons why the commissioner did not follow the assigned independent review organization's recommendation." MCL 550.1911(16)(b). The IRO's analysis is based on extensive experience, expertise, and professional judgment. The Commissioner can discern no reason why that judgment should be rejected in the present case. The Commissioner accepts the IRO reviewer's determination that Betahistine is experimental for treatment of the Petitioner's condition.

The Commissioner finds that BCN's denial of coverage for the compound prescription drug Betahistine was consistent with the terms of the prescription drug rider.

V. ORDER

The Commissioner upholds Blue Care Network's March 29, 2011, final adverse determination. BCN is not required to provide coverage for the prescription drug Betahistine.

This is a final decision of an administrative agency. Under MCL 550.1915, any person aggrieved by this Order may seek judicial review no later than 60 days from the date of this Order in the circuit court for the county where the covered person resides or in the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Commissioner of Financial and Insurance Regulation, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.